



# DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## EU Representative

SUNGO Europe B.V.  
Olympisch Stadion 24, 1076DE  
Amsterdam, Netherlands  
SRN: NL-AR-000000247

## Conformity Assessment

### Conformity Assessment Procedure

Annex II+III of Regulation (EU) 2017/745

### Applicable Standards

EN ISO 14971: 2019  
EN ISO 15223-1: 2021  
EN ISO 20417:2021  
EN ISO 10993-1: 2020  
EN ISO 10993-5: 2009  
EN ISO 10993-10: 2010  
EN 12184: 2014

### Remark

*The declaration of conformity is valid in connection with the release technical document CE/MDR-Y122127-01.*

*All the supporting documentation is retained at the premises of the manufacturer.*

*The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.*

## Manufacturer

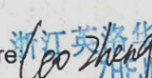
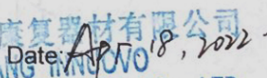

**Name:** Zhejiang Innuovo Rehabilitation Devices Co.,Ltd  
**Address:** No.196 Indusy Road, Hengdian Movie Zone, Dongyang, Zhejiang, China  
**SRN:** CN-MF-000008727

## Product Information

**Name:** Power Wheelchair  
**Model:** W5905(W5905-BLK)(#ACFPC17BLK),  
**GMDN:** 40840  
**Basic UDI-DI:** 697076597PW001QM  
Intended purpose: The product is intended to provide transportation for disabled or elderly persons limited to a seated position.  
**EMDN:** Y122127  
**Classification:** Class I, According to Rule 13, Annex VIII, Regulation (EU) 2017/745

## Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:  Date:   


Position: GM

Place: Zhejiang/China